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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,802	05/14/2001	Bojidar M. Stankov	1259-001	8869

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/854,802	<b>Applicant(s)</b> STANKOV, BOJIDAR M.	
	<b>Examiner</b> Frank I Choi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In view of the Appeal Brief filed on 1/20/2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2)

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 5/17/2000. It is noted, however, that applicant has not filed a certified copy of the MI2000A 001093 application as required by 35 U.S.C. 119(b).

#### ***Drawings***

Figure 1 is objected to because it is uncertain what is meant by "ore". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Specification***

The disclosure is objected to because of the following informalities:

Art Unit: 1616

Pg. 8, lines 7-23, the Amendment (12/9/2002) was incorrectly entered such that instead of lines 7-12 being substituted with the amendment and lines 17-23 being substituted with the amendment, lines 7-23 were substituted (See copy of page 8 of Specification). Since the file is now IFW and Examiner cannot physically correct the scanned image, please submit an appropriate correction.

Pg. 4, line 1, Pg. 5, line 1, the Amendment (12/9/2002) added the amendment "DETAILED DESCRIPTION OF THE INVENTION" to pg. 4, however, pg. 5 has the same heading.

Pg. 16, lines 21-33, Page 16 has both specification and a partial set of claims on the same page. The matter beginning with "CLAIMS" and ending with "both containing an" needs to be deleted from page 16 of the Specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the formulation set forth in Example 1, does not reasonably provide enablement for other formulations. The specification does not enable any person skilled in the

Art Unit: 1616

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

*The nature of the invention:*

The invention is directed to a nutritional food supplement tablet containing a slow release nucleus containing melatonin and hydroxypropylmethylcellulose (HPMC) and a fast release coating on said nucleus containing melatonin and HPMC and method of inducing and maintaining sleep with said tablet.

*The state of the prior art and the predictability or lack thereof in the art:*

The prior art of record does not appear to disclose the claimed invention. Further, the prior art indicates that HPMC is a known retardant and dose of drug and amount and type of excipients all have an effect on release rates (See Bromet et al. (US Pat. 5,879,710), Column 5, lines 1-5; Lee et al. (1999), pages 74-77). Applicant argues that the prior art does not exhibit the release profile of the claimed invention as represented by Figure 1, yet the claimed invention also contains HPMC, a known retardant. As such, it appears that predictability in the art is low.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification appears to provide only one formulation which exhibits the release profile which applicant argues is the exhibited by the claimed invention.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that the only mentioned components are HPMC and melatonin. As such, it appears that one of ordinary skill in the art would be required to do undue

Art Unit: 1616

experimentation in order to make and/or use the invention commensurate in scope with the claims, i.e. determining what other ingredients would result in the release profile of Figure 1.

Claims 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (2) granulation, (4) addition of the retardant excipients, lubricants, volume and gliding excipients and (7) application of the melatonin solution under pressure on the tablets for the formation of the "cortex". Specification discloses that stages (2), (4) and (7) are essential for the preparation of the formulations which are the subject of the invention (Pg. 8, lines 27, 28). Further, the compositions are directed to nutritional food supplement tablets, however, there is no limitation indicating that the composition contains a nutritional food supplement.

Claims 16-18, 20-21, 23,24 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 16-24 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Substitute Appeal Brief (1/20/2004). In that paper, applicant has stated that the claimed invention exhibits the plasma release profile in Figure 1 (Pg. 4). This statement indicates that the invention is different from what is defined in the claim(s) because the limitations "fast" and "slow" alone do not reflect this profile. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Claim Rejections - 35 USC § 102/103***

Art Unit: 1616

The rejection of Claims 16,18,19,21, 22 under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over, Lee et al. (1999) or Lee et al. (1997), respectively, is withdrawn.

The rejection of Claims 16-24 under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (1999) or Lee et al. (1997) in view of Bromet (US Pat. 5,879,710) or Flaugh (US Pat. 5,654,325) is withdrawn.

Examiner notes that the rejections are withdrawn solely because the Lee et al. references do not disclose the use of HPMC in the coating, i.e. cortex, and do not show the release of melatonin from the coating in 5-10 minutes.

### *Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

May 12, 2004



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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